DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 10, 2014

Valeris Medical
% Ms. Cheryl Wagoner
Principal Consultant
Wagoner Consulting LLC
P O Box 15729
Wilmington, North Carolina 28408

Re: K142230
Trade/Device Name: Apollo Suture Anchor System and Titan Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: August 8, 2014
Received: August 13, 2014

Dear Ms. Wagoner,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Special 510(k) Premarket Notification
Valeris Apollo Suture Anchor System and Titan Screws

Indications for Use

510(k) Number (if known): K142230

Device Name: Apollo Suture Anchor System and Titan Screws

Indications for Use:
The Apollo Suture Anchors and Titan Screws are indicated for use in fixation of ligament, tendon, bone, or soft tissue to bone in knee, shoulder, foot/ankle, elbow, and hand/wrist procedures. The screws are intended for use in the following procedures:

Indications – Apollo Medial Suture Anchor and Apollo XT Suture Anchors
The Apollo Medial Suture Anchor and Apollo XT Suture Anchors are intended for:

Shoulder
- ☐ Rotator Cuff Repair
- ☐ Bankart Repair
- ☐ SLAP Lesion Repair
- ☐ Biceps Tenodesis
- ☐ Acromio-Clavicular Separation Repair
- ☐ Deltoid Repair
- ☐ Capsular Shift or Capsulolabral Reconstruction

Foot/Ankle
- ☐ Lateral Stabilization
- ☐ Medial Stabilization
- ☐ Achilles Tendon Repair

Knee
- ☐ Medial Collateral Ligament Repair
- ☐ Lateral Collateral Ligament Repair
- ☐ Posterior Oblique Ligament Repair
- ☐ Illiotibial Band Tenodesis

Elbow
- ☐ Biceps Tendon Reattachment
- ☐ Ulnar or Radial Collateral Ligament Reconstruction

Hip
- ☐ Capsular Repair
- ☐ Acetabular Labral Repair

Indications – Apollo Lateral Anchor
The Apollo Lateral Anchor is indicated for:

Shoulder
- ☐ Rotator Cuff Repair
- ☐ Bankart Repair
- ☐ SLAP Lesion Repair
- ☐ Biceps Tenodesis
- ☐ Acromio-Clavicular Separation Repair
- ☐ Deltoid Repair
- ☐ Capsular Shift or Capsulolabral Reconstruction

Wrist/Hand
- ☐ Scapholunate Ligament Reconstruction
- ☐ Ulnar/Radial Collateral Ligament Reconstruction

Foot/Ankle
- ☐ Lateral Stabilization
- ☐ Medial Stabilization
- ☐ Achilles Tendon Repair/Reconstruction
- ☐ Hallux Valgus Reconstruction
- ☐ Mid- and Forefoot Reconstruction

Elbow
- ☐ Biceps Tendon Reconstruction
- ☐ Ulnar or Radial Collateral Ligament Reconstruction
- ☐ Lateral Epicondylitis Repair **(PEEK Anchor Only)**

Knee
- ☐ Medial Collateral Ligament Repair
- ☐ Lateral Collateral Ligament Repair
- ☐ Posterior Oblique Ligament Repair
- ☐ Joint Capsule Closure
- ☐ Iliotibial Band Tenodesis
- ☐ Patellar Ligament/Tendon Repair

Indications – Apollo Labral Suture Anchor

Shoulder
- ☐ Rotator Cuff Repair
- ☐ Bankart Repair
- ☐ SLAP Lesion Repair
- ☐ Biceps Tenodesis
- ☐ Acromio-Clavicular Separation Repair
- ☐ Deltoid Repair
- ☐ Capsular Shift or Capsulolabral Reconstruction

Special 510(k) Premarket Notification
Valeris Apollo Suture Anchor System and Titan Screws

Wrist
☐ Scapholunate Ligament Reconstruction

Elbow
☐ Biceps Tendon Reattachment
☐ Ulnar or Radial Collateral Ligament Reconstruction

Hip
☐ Capsular Repair
☐ Acetabular Labral Repair

Knee
☐ Extracapsular Repair
☐ Medial Collateral Ligament Repair
☐ Lateral Collateral Ligament Repair
☐ Posterior Oblique Ligament Repair
☐ Joint Capsule Closure
☐ Iliotibial Band Tenodesis Reconstruction
☐ Patellar Ligament/Tendon Repair
☐ Vastus Medialis Obliquus Muscle Advancement

Indications –Interference Screws

The Titan Interference Screws are indicated for the reattachment of ligament, tendon, soft tissue, or bone to bone during cruciate ligament reconstruction surgeries of the knee. All screws with a diameter of 9 mm or less and a length of 23 mm or less are also intended for the use in the following procedures:

Knee
☐ ACL repairs
☐ PCL repairs
☐ Extra-capsular repairs
o Medial collateral ligament
o Lateral collateral ligament
o Posterior oblique ligament
☐ Patellar realignment and tendon repairs
o Vastus medialis oliquous advancement
☐ Iliotibial band tenodesis

Shoulder
☐ Capsular stabilization
o Bankart repair
o Anterior shoulder instability
o SLAP lesion repairs
o Capsular shift of capsulolabral reconstructions
☐ Acromioclavicular separation repairs
☐ Deltoid repairs
☐ Rotator cuff tear repairs
☐ Biceps tenodesis

Foot and Ankle
☐ Hallux valgus repairs
☐ Medial or lateral instability repairs/reconstructions
☐ Achilles tendon repairs/reconstructions
Midfoot reconstructions
☐ Metatarsal ligament/tendon repairs/reconstructions
☐ Bunionectomy
☐ Flexor Hullucis Longus
☐ Tendon transfers

Elbow, Wrist, and Hand
☐ Biceps tendon reattachment
☐ Ulnar or radial collateral ligament reconstructions
☐ Lateral epicondylitis repair

Indications –Titan Mini-Interference Screws

The Titan Mini-Interference Screws are intended to be used for fixation of tissue, including ligament or tendon to bone, or a bone/tendon to bone. See below for specific indications.
The Mini-Interference Screws are intended to provide soft tissue reattachment (i.e. fixation of ligament and tendon graft tissue).
See below for specific indications.

Shoulder
☐ Capsular stabilization
o Bankart repair
o Anterior shoulder instability
o SLAP lesion repairs
o Capsular shift of capsulolabral reconstructions
☐ Acromioclavicular separation repairs
☐ Deltoid repairs
☐ Rotator cuff tear repairs
☐ Biceps tenodesis

Foot and Ankle
☐ Hallux valgus reconstruction
☐ Medial stabilization
☐ Lateral stabilization
☐ Achilles Tendon Repair
☐ Midfoot reconstructions
☐ Metatarsal ligament repair
☐ Bunionectomy
☐ Flexor Hullucis Longus for Achilles Tendon reconstruction
☐ Tendon transfers in the foot and ankle

Knee
☐ Medial Collateral Ligament Repair
Lateral Collateral Ligament Repair
☐ Patellar Tendon Repair
☐ Posterior Oblique Ligament Repair
☐ Illiotibial Band Tenodesis
☐ Posterior Cruciate Ligament Repair

Elbow
☐ Biceps tendon reattachment
☐ Ulnar or radial collateral ligament reconstruction

Special 510(k) Premarket Notification
Valeris Apollo Suture Anchor System and Titan Screws

☐ Scapholunate ligament reconstruction ☐ Tendon transfers	**Wrist and Hand** ☐ Scapholunate Ligament Reconstruction ☐ Ulnar Collateral Ligament Reconstruction ☐ Radial Collateral Ligament Reconstruction ☐ Carpometalcarpal joint arthroplasty (basal thumb joint arthroplasty) ☐ Carpal Ligament Reconstructions and repairs ☐ Tendon transfer in the hand/wrist ☐ Lateral Epicondylitis repair

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Special 510(k) Premarket Notification
Valeris Apollo Suture Anchor System and Titan Screws

510(k) Summary
(as required by 21 CFR 807.92)

Submitter	Valeris Medical
Address	200 Cobb Pkwy N Building 200, Suite 210 Marietta, GA 30062
Telephone	888-404-3980 Ext 101
Fax	678-669-2188

Contact Person	Daniel Lanois General Manager
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Telephone	888-404-3980 Ext 101
Fax	678-669-2188
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Date Prepared	August 8, 2014

Trade Name	Apollo Suture Anchor System and Titan Screws
Common Name	Screw, Fixation, Bone
Panel Code	Orthopaedics/87
Classification Name	Smooth or threaded metallic bone fixation fastener
Class	Class II
Regulation Number	21 CFR 888.3040
Product Code	MBI

Name of Predicate Device	**510(k) #**	**Manufacturer**
Apollo Suture Anchor System and Titan Screws	K133036	Amendia (transferred product to Valeris Medical)

Description	<u>Apollo Family</u> The Apollo Medial Suture Anchor, XT Suture Anchor, Lateral Anchor, and Labral Suture Anchor are delivery systems for anchors for use in fixation of ligament, tendon, bone, or soft tissue to bone in knee, shoulder, foot/ankle, elbow, and hand/wrist procedures. These anchors consist of cannulated anchors with integrated suture attachment or separate suture punch eyelet. The Anchors are provided loaded on individual inserters with and without integrated sutures, sterile, for single use only. <u>Titan Family</u> The Titan Interference and Mini-Interference Screws are interference screws for use in fixation of ligament, tendon, bone, or soft tissue to bone in knee, shoulder, foot/ankle, elbow, and hand/wrist procedures. The screws are provided sterile, for single use only. Screw and anchor implants are made from either a titanium alloy (6Al4V) per ASTM F136, or PEEK (Zeniva ZA-500) per ASTM F2026 from Solvay Advanced Polymers.

Special 510(k) Premarket Notification
Valeris Apollo Suture Anchor System and Titan Screws

Indications and Intended Use	The Apollo Suture Anchors and Titan Screws are indicated for use in fixation of ligament, tendon, bone, or soft tissue to bone in knee, shoulder, foot/ankle, elbow, and hand/wrist procedures. The screws are intended for use in the following procedures:

Indications – Apollo Medial Suture Anchor and Apollo XT Suture Anchors

The Apollo Medial Suture Anchor and Apollo XT Suture Anchors are intended for:

Shoulder
- ☐ Rotator Cuff Repair
- ☐ Bankart Repair
- ☐ SLAP Lesion Repair
- ☐ Biceps Tenodesis
- ☐ Acromio-Clavicular Separation Repair
- ☐ Deltoid Repair
- ☐ Capsular Shift or Capsulolabral Reconstruction

Foot/Ankle
- ☐ Lateral Stabilization
- ☐ Medial Stabilization
- ☐ Achilles Tendon Repair

Knee
- ☐ Medial Collateral Ligament Repair
- ☐ Lateral Collateral Ligament Repair
- ☐ Posterior Oblique Ligament Repair
- ☐ Illiotibial Band Tenodesis

Elbow
- ☐ Biceps Tendon Reattachment
- ☐ Ulnar or Radial Collateral Ligament Reconstruction

Hip
- ☐ Capsular Repair
- ☐ Acetabular Labral Repair

Indications – Apollo Lateral Anchor

The Apollo Lateral Anchor is indicated for:

Shoulder
- ☐ Rotator Cuff Repair
- ☐ Bankart Repair
- ☐ SLAP Lesion Repair
- ☐ Biceps Tenodesis
- ☐ Acromio-Clavicular Separation Repair
- ☐ Deltoid Repair
- ☐ Capsular Shift or Capsulolabral Reconstruction

Wrist/Hand
- ☐ Scapholunate Ligament Reconstruction
- ☐ Ulnar/Radial Collateral Ligament Reconstruction

Foot/Ankle
- ☐ Lateral Stabilization
- ☐ Medial Stabilization
- ☐ Achilles Tendon Repair/Reconstruction
- ☐ Hallux Valgus Reconstruction
- ☐ Mid- and Forefoot Reconstruction

Elbow
- ☐ Biceps Tendon Reconstruction
- ☐ Ulnar or Radial Collateral Ligament Reconstruction
- ☐ Lateral Epicondylitis Repair **(PEEK Anchor Only)**

Knee
- ☐ Medial Collateral Ligament Repair
- ☐ Lateral Collateral Ligament Repair
- ☐ Posterior Oblique Ligament Repair
- ☐ Joint Capsule Closure
- ☐ Iliotibial Band Tenodesis
- ☐ Patellar Ligament/Tendon Repair

Indications – Apollo Labral Suture Anchor

Shoulder
- ☐ Rotator Cuff Repair
- ☐ Bankart Repair
- ☐ SLAP Lesion Repair
- ☐ Biceps Tenodesis
- ☐ Acromio-Clavicular Separation Repair
- ☐ Deltoid Repair
- ☐ Capsular Shift or Capsulolabral Reconstruction

Wrist
- ☐ Scapholunate Ligament Reconstruction

Elbow
- ☐ Biceps Tendon Reattachment
- ☐ Ulnar or Radial Collateral Ligament Reconstruction

Hip
- ☐ Capsular Repair
- ☐ Acetabular Labral Repair

Knee

- ☐ Extracapsular Repair
- ☐ Medial Collateral Ligament Repair
- ☐ Lateral Collateral Ligament Repair
- ☐ Posterior Oblique Ligament Repair
- ☐ Joint Capsule Closure
- ☐ Iliotibial Band Tenodesis Reconstruction
- ☐ Patellar Ligament/Tendon Repair
- ☐ Vastus Medialis Obliquus Muscle Advancement

Indications –Interference Screws

The Titan Interference Screws are indicated for the reattachment of ligament, tendon, soft tissue, or bone to bone during cruciate ligament reconstruction surgeries of the knee. All screws with a diameter of 9 mm or less and a length of 23 mm or less are also intended for the use in the following procedures:

Knee

- ☐ ACL repairs
- ☐ PCL repairs
- ☐ Extra-capsular repairs
  - o Medial collateral ligament
  - o Lateral collateral ligament
  - o Posterior oblique ligament
- ☐ Patellar realignment and tendon repairs
  - o Vastus medialis oliquous advancement
- ☐ Iliotibial band tenodesis

Shoulder

- ☐ Capsular stabilization
  - o Bankart repair
  - o Anterior shoulder instability
  - o SLAP lesion repairs
  - o Capsular shift of capsulolabral reconstructions
- ☐ Acromioclavicular separation repairs
- ☐ Deltoid repairs
- ☐ Rotator cuff tear repairs
- ☐ Biceps tenodesis

Foot and Ankle

- ☐ Hallux valgus repairs
- ☐ Medial or lateral instability repairs/reconstructions
- ☐ Achilles tendon repairs/reconstructions
  Midfoot reconstructions
- ☐ Metatarsal ligament/tendon repairs/reconstructions
- ☐ Bunionectomy
- ☐ Flexor Hullucis Longus
- ☐ Tendon transfers

Elbow, Wrist, and Hand

- ☐ Biceps tendon reattachment
- ☐ Ulnar or radial collateral ligament reconstructions
- ☐ Lateral epicondylitis repair
- ☐ Scapholunate ligament reconstruction
- ☐ Tendon transfers

Indications –Titan Mini-Interference Screws

The Titan Mini-Interference Screws are intended to be used for fixation of tissue, including ligament or tendon to bone, or a bone/tendon to bone. See below for specific indications.

The Mini-Interference Screws are intended to provide soft tissue reattachment (i.e. fixation of ligament and tendon graft tissue).

See below for specific indications.

Shoulder

- ☐ Capsular stabilization
  - o Bankart repair
  - o Anterior shoulder instability
  - o SLAP lesion repairs
  - o Capsular shift of capsulolabral reconstructions
- ☐ Acromioclavicular separation repairs
- ☐ Deltoid repairs
- ☐ Rotator cuff tear repairs
- ☐ Biceps tenodesis

Foot and Ankle

- ☐ Hallux valgus reconstruction
- ☐ Medial stabilization
- ☐ Lateral stabilization
- ☐ Achilles Tendon Repair
- ☐ Midfoot reconstructions
- ☐ Metatarsal ligament repair
- ☐ Bunionectomy
- ☐ Flexor Hullucis Longus for Achilles Tendon reconstruction
- ☐ Tendon transfers in the foot and ankle

Knee

- ☐ Medial Collateral Ligament Repair
  Lateral Collateral Ligament Repair
- ☐ Patellar Tendon Repair
- ☐ Posterior Oblique Ligament Repair
- ☐ Illiotibial Band Tenodesis
- ☐ Posterior Cruciate Ligament Repair

Elbow

- ☐ Biceps tendon reattachment
- ☐ Ulnar or radial collateral ligament reconstruction

Wrist and Hand

- ☐ Scapholunate Ligament Reconstruction
- ☐ Ulnar Collateral Ligament Reconstruction
- ☐ Radial Collateral Ligament Reconstruction
- ☐ Carpometalcarpal joint arthroplasty (basal thumb joint arthroplasty)
- ☐ Carpal Ligament Reconstructions and repairs
- ☐ Tendon transfer in the hand/wrist
- ☐ Lateral Epicondylitis repair

Technological Characteristics and Substantial Equivalence	Documentation was provided to demonstrate that the Subject device, Apollo Suture Anchor System and Titan Screws is substantially equivalent to the Predicate Apollo Suture Anchor System and Titan Screws (K133036), The Subject device is substantially equivalent to the predicate device in intended use, indications for use, materials, technological characteristics, and labeling.

Performance Data	Axial Pull-Out and Insertion Torque per ASTM F543-7 testing were conducted to confirm that the modification to add a 3rd suture portal did not introduce any new risk.

Conclusion	Based on the indications for use, technological characteristics, materials, and comparison to predicate devices, the Subject Apollo Suture Anchor System and Titan Screws has been shown to be substantially equivalent to legally marketed predicate devices, and is safe and effective for its intended use.